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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,445	06/11/2001	Gregory R. Mundy	OSTS:003USD2	4570

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/07/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,445

Applicant(s)

MUNDY ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,27,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,30 and 31 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed May 21, 2003 is acknowledged. Claims 25 and 27 were amended. Claims 26, 28 and 29 were canceled. Claims 30 and 31 were added.

Claims 25, 27, 30 and 31 are pending and examined on the merits.

Objections and Rejections Withdrawn:

2. The objection to the drawings is withdrawn in view of the submission of a corrected Figure 4.

3. The objection to claim 25 is withdrawn in view of the amendment.

4. The rejection of claims 25, 27 and 29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to claim 25.

For clarity of the record, it is noted that claims 26-29, were previously rejected under 35 U.S.C. 112, 2nd paragraph because they were dependent from claim 25, and dependent claims are rendered indefinite when the parent claim is indefinite.

5. The rejection of claims 25 and 28 under 35 U.S.C. 102(b) as being anticipated by Pirola (Pirola et al, Journal of Biological Chemistry, 268(3): 1987-1994, 1993) is withdrawn in view of the amendment to claim 25 and the cancellation of claim 28.

Art Unit: 1642

6. The rejection of claim 25 under 35 U.S.C. 102(b) as being anticipated by Topping (Topping et al, Endocrinology, 131(1): 5-13, 1992) is withdrawn in view of the amendment to claim 25.

8. The rejection of claims 25, 26 and 28 under 35 U.S.C. 102(b) as being anticipated by Allinson (Allinson and Drucker, Cancer Res. 52: 3103-3109, 1992) is withdrawn in view of the amendment to claim 25, so that claim 25 is drawn to a method of in vivo treatment.

Allinson teaches a method of inhibiting the expression of PTH-rP by the addition of dexamethasone to cultures of keratinocytes.

10. The rejection of claims 25 and 26 under 35 U.S.C. 102(a) as being anticipated by Rabbani (Rabbani et al, Endocrinology, 136(12): 5416-5422, 1995, Dec.) is withdrawn in view of the amendment to claim 25 and the cancellation of claim 26.

11. The rejection of claims 25, 26 and 28 under 35 U.S.C. 102(b) as being anticipated by Deftos (Deftos et al, Endocrinology, 125: 563-565, 1989, ABSTRACT only) are withdrawn in view of the amendment.

12. The rejection of claim 25 under 35 U.S.C. 102(b) as being anticipated by Yamaguchi (U.S. Patent 5,246,700; issued September 21, 1993) is withdrawn in view of the amendment.

Art Unit: 1642

New Grounds of Rejection:

The following new grounds of rejection were necessitated by amendment.

13. Claims 25, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Suda (U.S. Patent 4,391,802; issued July 5, 1983) as evidenced by Falzon (Falzon, M. et al. Endocrinology, 139(3): 1046-1053, 1998).

Falzon teaches that 1,25-(OH)₂D₃ down regulates PTHrP gene expression at the transcriptional level, via promoter 1 (see page 1050, col. 1).

Claims 25, 30 and 31 are drawn to methods comprising the administration of a compound that down regulated parathyroid hormone related peptide production through inhibition of the PTH-rP promoter. Claims 30 and 31 add the limitations that the administration may be repeated, that the administration may be oral or intravenous.

Suda teaches a method of treating leukemia, comprising administering 1 α ,25-dihydroxyvitamin D₃. The administration may oral, and is repeated daily (see claims 1, 2, 3, 7, and col. 5, lines 29-54). Thus, Suda teaches a method that is the same as that claimed.

Conclusion

Claim 27 is objected to for depending from a rejected claim. Claim 27 is free of the art and would be allowable if written as an independent claim. No claim is allowed.

Art Unit: 1642

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
October 3, 2003


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